

to the requirements of § 73.575(a)(1) and (b).

(2) Color additive mixtures for drug use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs, and the following: Silicon dioxide, SiO₂, and/or aluminum oxide, Al₂O₃, as dispersing aids—not more than 2 percent total.

(b) *Uses and restrictions.* The color additive titanium dioxide may be used for coloring ingested and externally applied drugs generally, in amounts consistent with good manufacturing practice. External application includes use in the area of the eye.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of the chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1645 Aluminum powder.

(a) *Identity.* (1) The color additive aluminum powder shall be composed of finely divided particles of aluminum prepared from virgin aluminum. It is free from admixture with other substances.

(2) Color additive mixtures for external drug use made with aluminum powder may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Aluminum powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 200-mesh screen and 95 percent shall pass through a 325-mesh screen.

Mercury, not more than 1 part per million.

Arsenic, not more than 3 parts per million.

Lead, not more than 20 parts per million.

Aluminum, not less than 99 percent.

(c) *Uses and restrictions.* Aluminum powder is safe for use in externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

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§ 73.1646 Bronze powder.

(a) *Identity.* (1) The color additive bronze powder is a very fine metallic powder prepared from alloys consisting principally of virgin electrolytic copper and zinc with small amounts of the virgin metals aluminum and tin. It contains small amounts of stearic or oleic acid as lubricants.

(2) Color additive mixtures for drug use made with bronze powder may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Bronze powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Stearic or oleic acid, not more than 5 percent.

Cadmium (as Cd), not more than 15 parts per million.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Aluminum (as Al), not more than 0.5 percent.

Tin (as Sn), not more than 0.5 percent.

Copper (as Cu), not more than 95 percent and not less than 70 percent.

Zinc (as Zn), not more than 30 percent.

Maximum particle size 45μ (95 percent minimum).